US ERA ARCHIVE DOCUMENT

## Product Performance Data Evaluation Review by Kevin Sweeney, Entomologist, IB

Henry Jenen 6/3/03

Date: June 13, 2003

Reviewer: Joseph Tavano

EPA Reg. No./File Symbol: 51147-T and 51147-A

Products: (-T) Deet Insect Repellent 30 and (-A) Deet Insect Repellent 10

Registrant: Morflex

PM: Marion Johnson, PM 10

Chemical: DEET

PC code: 080301

Active ingredient Concentration: (-A) 10% DEET and (-T) 30% DEET

Application type: repellent

Site: human skin

Pests: Mosquitoes and other biting flies listed on the label, ticks, chiggers, fleas, and red bugs.

**OPPTS Testing Guideline: 810.33** 

GLP: Yes

Study: MRID 45776902 entitled Evaluation of Two Experimental Morflex Repellent Formulations and Ultrathon against Adult Mosquitoes in the Field during July 2002. Study performed by Roy Ellis and Randy Gadawski, Prairie Pest Management, Carman, MB Canada

This study was conducted in accordance with GLP as described in Part 160 40CFR. Three formulations were evaluated in this study, the two subject products and Ultrathon. Ultrathon is a registered 3M product that generally provides extended protection against biting insects and in this experiment it served as the positive control. The study was conducted in the field in Carman, Manitoba Canada.

Four human test subjects were treated with repellent. A fifth test subject served as the untreated control. Treatments were randomly assigned to subjects in a "round-robin" scheme to negate human subject level effects on the experimental results. Subjects sat in chairs during the

exposure. The end-use product formulations (all creams) were applied at the rate of 1.5g/600sq.cm of exposed skin surface. Only the forearm was treated.

The minimum biting count at the test sites was 5 adult mosquito bites/minute. All biting/probing mosquitoes were collected, frozen, and identified to species. Both the First Confirmed Bite test yielding a Complete Protection Time (CPT) and the 95% level of bite reduction test were conducted and used to evaluate the respective repellent products in this study. The confidence interval was 95% with a maximum probability for a Type-I error set at 0.05. Data were subjected to a one-way ANOVA, Means Comparisons, Regression and Correlation tests.

The data showed that there were no significant statistical difference between the 30% Morflex product and Ultrathon repellent. Both the 30% Deet Morflex repellent and Ultrathon provided much better protection than the 10% DEET Morflex product. 95% protection times were much higher but the same differences existed between products as described above.

## The protection times were:

A CONTRACTOR OF THE PARTY OF TH

```
30% DEET Morflex product (-T) = 95% PT of 13.8 hours; CPT of 7.2 hours.
10% DEET Morflex product (-A) = 95% PT of 4.5 hours; CPT of 3.7 hours.
Ultrathon = 95% PT of 13.9 hours; CPT of 8.9 hours.
```

## Recommendations:

- 1. The submitted study is acceptable and supports the label claims for mosquitoes for the subject products. Protection/repellency times should be based on the CPT only.
- 2. The formulations tested in this study were creams. The Master Label submitted for these products includes pumps (aerosols?), pump-sprays, cream, towelettes, and squeeze bottles. However, there is only one Basic CSF. Are all of the supplemental distributor formulations the same? I don't see how they can be. I don't believe that these CPTs should support other formulations unless they are substantially similar.